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EXAMINER	
BAUSCH, SARAE L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,102	CAUFIELD ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27 and 29-36* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner reviewing your application at the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Sarae Bausch.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 1-27 and 29-36, drawn to method of surveillance, classified in class 435, subclass 6.

   II. Claim 28, drawn to system, classified in class 425, subclass 288.1.

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of group I can be practiced by hand without the use of the apparatus and the apparatus of group II can be used to genotype an individual that is not required for the method of group I. Furthermore a search for a method of surveillance is not coextensive with a search for a system for surveillance.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species: biological, chemical, and radiological agents. The species are independent or distinct because the agents are structurally and functionally distinct. Each of the different agents have different structures and functions, for example a biological agent can comprise a living organism that replicates in a host organism, while a chemical agent can comprise an organic compound that attacks a biological pathway, while a radiological agent comprises exposing a host to radiation which causes mutagenic mechanism in the host.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-3, 6-16, 22-27 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. During a telephone conversation with Juliet Switzer and Jason Chumney on 06/09/2005 a provisional election was made with traverse to prosecute the invention of group I and the species biological agents, claims 1-27 and 29-36. Affirmation of this election must be made by applicant in replying to this Office action. Claim 28 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

9. The drawings are acceptable.

Specification

10. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

other form of browser-executable code. See MPEP § 608.01. Page 17 and 21 of the specification contain embedded hyperlinks.

Claim Objections

11. Claim 4 is objected to because of the following informalities: claim 4 does not contain a period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112- Second Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-27 and 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a). Claim 1-27 are drawn to a method of surveillance, however the final process step in claim 1 is assaying a sample derived from materials collected from a sample domain wherein the sample domain comprises at least one collection point from which the materials are collected in a pre-existing operation unrelated to surveillance. .Accordingly the claims are ambiguous because the preamble recites a limitation that is not recited in any of the process steps and it is unclear the metes and bounds of the claims. Applicant should amend the claims to indicate how the step of assaying a sample results in method of surveillance.

(b). Claim 6-9 is vague and indefinite for the recitation of "derived from a street sweeper machine" in claim 6. It is unclear what the term "derived" encompasses as derived is vague and indefinite. It is unclear if the sample is obtained from a street sweeper machine, taken from the sample domain to the test facility in a street sweeper machine, or if the sample include components of the street sweeper.

(c). Claim 4 is vague and indefinite. Claim 4 recites assaying for Bacillus anthracis in the sample and introducing Tetrahymena pyriformis to the sample. There is no active process step that uses the Tetrahymena. It is unclear how the introduction of Tetrahymena further limits the claim and how the addition of tetrahymena results in a method of surveillance.

(d). Claims 17-21 are vague and indefinite. Claim 17 is drawn to assaying for the presence of a biological agent comprising introducing Tetrahymena pyriformis to the sample. There is no active process step that uses the Tetrahymena to assay for the biological agent. It is unclear how the introduction of Tetrahymena further limits the claim and how the addition of tetrahymena to the sample results in assaying for biological agent and a method of surveillance.

(e). Claims 29-36 are vague and indefinite. Claim 29 is drawn to a method for determining the presence of a Bacillus spore comprising introducing Tetrahymena pyriformis to the sample and assaying the sample for the presence of the Bacillus spore. There is no active process step that uses Tetrahymena. It is unclear how the addition of Tetrahymena to the sample allows for the detection of the Bacillus spore. It is unclear how the addition of tetrahymena limits the claim and results in detection of a bacillus spore.

(f). Claims 32-36 are vague and indefinite. Claims 32, 34 and 35 require introducing the sample to a first or second membrane at a temperature effective to kill vegetative bacteria.

Claims 33 and 36 require the temperature effective to kill vegetative bacteria is about 70 to 80C. However, it is unclear how the introduction of the sample to the first or second membrane at a temperature to kill vegetative bacteria results in identification of bacillus spores by addition of tetrahymena. It is unclear if the vegetative bacteria that is killed is the bacillus or tetrahymena and it is unclear how this results in identification of bacillus spores.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-3, 11-16, and 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Cordery et al. (US 6613571, filed Dec 19, 2001).

With regard to claim 1, Cordery et al. teach a method for detecting biological hazards in mail at point of entry (see column 2, lines 54-58). Cordery et al. teach assaying incoming mail for the presence of biological agents (see column 4, lines 59-65).

With regard to claim 2-3, 11, Cordery et al. teach assaying incoming mail for the presence of biological agents. Incoming mail can be collected from mailboxes situated on public streets (predetermined patter and brought to central location, claim 11) (see column 2, lines 63-

67 and claim 11 of '571) therefore the mail that is collected by Cordery et al. is from a route undertaken by a street sweeper machine and is a predetermined traceable route.

With regard to claim 12-16, Cordery et al. teach collecting the mail (collected in a predetermined pattern and brought to central location, claim 12) and detecting hazardous mail by importing the mail piece into a segregated mail sample, collecting air samples, testing the air sample for hazards, if a hazard is present (increase in level of biological agent) then the process ends if no hazard is present (decreases in level of biological agent) then the mail pieces are transported to a collection chamber (see column 7, lines 13-25).

With regard to claim 22-24, Cordery et al. teach collecting the mail and detecting hazardous mail by collecting air samples from the mail (collection integrity is preserved and assaying a sample is from within the collection bin). Cordery et al. teach that if a hazard is present then the process ends (in communication with collection bin) (see column 7, lines 13-25).

With regard to claim 25-27, Cordery et al. teach detecting hazards in mail using incoming mail receptacle (collection bin), detecting the presence of mail piece collecting air samples, testing air samples for hazards by PCR or UV detection and determining if a hazard is present in the mail (see claim 11 of '571, column 5, lines 23-40 and column 7 lines 13-25).

16. Claims 1, 12-13, 15-17, 19-21, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Manasherob et al. (App. Envir. Microbio. 1998, 64: 1750-1758).

With regard to claim 1, 17, 19-21, Manasherob et al. teach a method of determining spores of Bacillus thuringiensis (biological agent) (claim 19-21) (method of surveillance) in mosquito larvae (sample collected from a sample domain) by addition of T. pyriformis cells (claim 17) (see bioencapsulation, page 1750 and bioassay page 1751).

With regard to claim 12-13 and 15-16, Manasherob et al. teach a method of determining B. thuringiensis spores in mosquito larvae, comparing to different levels of spores in mosquito larvae of ingested T. pyriformis (increase, decrease, and normal levels of spores in food vacuoles of larvae) (see figure 4).

With regard to claim 29 and 31, Manasherob et al. teach a method of determining the spores of Bacillus thuringiensis (claim 31) by adding Tetrahymena pyriformis to a sample. Manasherob et al. teach washed T. pyriformis cells were incubated with B. thuringiensis (see bioencapsulation, column 2, page 1750). Manasherob et al. teach identification of B. thuringiensis in food vacuoles of T. pyriformis cells (see figure 2 and page 1755, 2nd column, 1st full paragraph).

17. Claims 1-3, 5-16 and 22-27 rejected under 35 U.S.C. 102(a) as being anticipated by Hoffmaster et al. (Emerging Inf. Diseases, 2002, Vol 8, No. 10, supplement, p. 1-12).

With regard to claim 1-3, 6-11, and 22-24, Hoffmaster et al. teach evaluation and validation of RT-PCR for identification of Bacillus anthracis in environmental samples (See page 1, 2nd paragraph). Hoffmaster et al. teach elution of swab specimens and environmental samples in a aqueous solution (collection integrity is preserved, claim 22) (claim 10) (see page 2, last paragraph cont'd to page 3). Hoffmaster et al. teach a wide variety of samples were tested including vacuum cleaner debris (sample derived from a street sweeper machine, claim 3, 6-9, 11) (sample from within a collection bin, claim 23-24) (see Real-time PCR in environmental samples, page 5).

With regard to claim 5, Hoffmaster et al. teach real-time PCR to detect B. anthracis (see page 1, 2nd full paragraph).

With regard to claim 12-16, Hoffmaster et al. teach testing the environmental sample by PCR and culture to determine the presence of B. anthracis. Hoffmaster teaches that 35 samples were positive by both methods and only 7 were positive by culture only, 4 positive by PCR only (see Real-time PCR in environmental samples, page 5 and page 7, last two paragraphs). Therefore, Hoffmaster, teaches assaying for the presence of a biological agent by comparing the level to a normal level (claim 12-14) (positive result in either PCR or culture). Hoffmaster teaches assaying for an increase or decrease relative to an earlier assay (claim 15-16) (PCR versus culture assay).

With regard to claim 25-27, Hoffmaster et al. each testing environmental samples by PCR by elution of swab specimens and environmental samples in an aqueous solution (see page 2, last paragraph con't to page 3). Hoffmaster et al. teach testing the environmental specimens by real time PCR for the detection of B. anthracis (biological agent) (see real time PCR of environmental specimens, page 5). Hoffmaster et al. teach reporting the results of the PCR analysis of the samples (see page 5 and page 7).

Conclusion

18. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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CARLA J. MYERS
PRIMARY EXAMINER

Sarae Bausch, PhD.
Examiner
Art Unit 1634